UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES
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<u>Ex parte</u> CHARLES RICHTER KING,
PATRICIA SCHRIVER STEEG
and LANCE A. LIOTTA
_____

Appeal No. 1997-3461
Application No. 07/806,932
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ON BRIEF
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Before WINTERS, WILLIAM F. SMITH, and ADAMS, <u>Administrative Patent Judges,</u>

ADAMS, <u>Administrative Patent Judge</u>.

<u>DECISION ON APPEAL</u>

This is a decision on the appeal under 35 U.S.C. ' 134 from the examiner's final

rejection of claims 22, 23, 25 and 26.

1

Claim 22 is illustrative of the subject matter on appeal and is reproduced below:

22. An isolated polynucleotide molecule encoding a human nm23 protein, said polynucleotide molecule having a nucleotide sequence selected from the group consisting of nm23-H1 (SEQ ID NO:2) and nm23-H2S (SEQ ID NO:4).

The references relied upon by the examiner are:

Steeg et al. (Steeg I)	5,049,662	Sep. 17, 1991
Mullis et al. (Mullis)	4,683,195	Jul. 28, 1987
Steeg et al. (Steeg II)[1]	Re. 35,097	Nov. 21, 1995

Steeg et al. (Steeg III), "Evidence for a Novel Gene Associated With Low Tumor Mestastatic Potential," J. National Cancer Institute, Vol. 80, pp. 204-208 (1988)

Bevilacqua et al., (Bevilacqua), "Association of Low nm23 RNA Levels in Human Primary Infiltrating Ductal Breast Carcinomas with Lymph Node Involvement and Other Histopathological Indicators of High Metastatic Potential," Cancer Research, Vol. 49, pp. 5185-5190 (1989)

GROUNDS OF REJECTION[2]

Claims 22, 23, 25 and 26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of Steeg I in view of Mullis.

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[1] Steeg II issued from Application No. 08/048,136, and is a reissue application of United States Patent No. 5,049,662 (Steeg I).
[2] We note the examiner withdrew the rejections over claim 24 in the examiner's Answer. We further note the examiner's indication that claim 24 "is allowable as written" in the examiner's letter (Paper No. 34, mailed July 29, 1996).

Claims 22, 23, 25 and 26 are provisionally rejected under the judicially created

doctrine of obviousness-type double patenting as being unpatentable over claims 1-4

of copending application Steeg II in view of Mullis.[3]

Claims 22, 23, 25 and 26 are rejected under 35 U.S.C. ' 103 as being

unpatentable over Steeg I in view of Mullis, or the combination of Steeg III and

Bevilacqua in view of Mullis.

We reverse.

DISCUSSION

In reaching our decision in this appeal, we have given careful consideration to

the appellants' specification and claims, and to the respective positions articulated by

the appellants and the examiner. We make reference to the examiner=s Answer (Paper

No. 32, mailed May 10, 1996), for the examiner=s reasoning in support of the rejection.

We further reference appellants' Brief (Paper No. 31, filed February 21, 1996) and

appellants' Reply Brief (Paper No. 33, filed July 10, 1996), for the appellants'

arguments in favor of patentability.

The examiner's basis for each rejection is that the cDNA sequence for murine

nm23 is known, this murine cDNA sequence has been shown to detect human nm23,

and the prior art recognizes that nm23 is differentially expressed in low vs. high

metastatic cells. See, Answer, pages 4-6. The examiner therefore reasons that an

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[3] We note the examiner's reference to 08/048,136, matured into Re. 35,097, therefore
this rejection is no longer provisional.

"artisan would have found it *prima facie* obvious to have screened a cDNA library made from human breast cell carcinoma mRNA with the cDNA encoding murine nm23 of the '662 patent to permit the characterization of human nm23 at the molecular level." See e.g., Answer, pages 4 and 6.

Appellants respond to the examiner's rejection by stating that "[t]he existence of two human nm23 genes which encode two different human nm23 proteins is not taught or suggested by the cited references." See, Brief, page 3. In the Brief, bridging paragraph of pages 3-4, appellants point out that "[a]s taught at page 3 of the specification, these are 'two different and distinct human genes … which encode … two different and distinct nm23 proteins." Because the cited references do not teach or suggest the existence of two human nm23 genes, they cannot render the instant claims obvious."

In response to appellants' arguments the examiner argues that in contrast to the appellants' specification, claims and argument, two human nm23 genes do not exist. The examiner reasons that "an nm23 gene, by definition, is differentially expressed in tumor cells of differing metastatic potential[4]." See, Answer, page 7. Based on this definition, the examiner further reasons that the identification of a second nm23 gene is "clearly an erroneous conclusion." See, Answer, page 7. The examiner concludes at page 8 of the Answer that "nm23-H2 is not differentially expressed in tumor cells of

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[4] We recognize that the examiner failed to identify any support for this definition of "an nm23 gene."

4

differing metastatic potential and, therefore, it is not encompassed by the term "nm23" as defined by the examiner. After reasoning that only one nm23 gene exists, the examiner concludes that "[t]he very basis of the pending rejections is that the human nm23 **is** an obvious species variation of murine nm23." See, Answer, page 11.

For a number of reasons appellants refute the examiner's conclusion that only one nm23 gene exists. See generally, Reply Brief. At page 5 of the Reply Brief, appellants cites to the bridging paragraph of pages 3 and 4 of the specification which describes nm23 as follows "[a]pplicant has presently found two different and distinct human genes (DNA) which encode for two different and distinct nm23 proteins. The first gene is referred to herein as nm23-H1. The second gene is referred to herein as nm23-H2S."

We remind the examiner that "[t]he Patent Office has the initial duty of supplying the factual basis for its rejection. It may not, because it may doubt that the invention is patentable, resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in its factual basis." In re Warner, 379 F.2d 1011, 1017, 154 USPQ 173, 178 (CCPA 1967), cert. denied, 389 U.S. 1057 (1968). Therefore, we are not persuaded by the examiner's speculation regarding the appropriate definition of "an nm23 gene" which clearly conflicts with the record in this case.

We emphasize that the initial burden of establishing reasons for unpatentability rests on the examiner. In re Oetiker, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445

(Fed. Cir. 1992). Once the examiner's speculation regarding the differences between

nm23-H1 and nm23H2S is removed, it is clear that the examiner's treatment of the

claims on appeal lacks a reason, suggestion or motivation, stemming from the prior art,

which would have led a person having ordinary skill to the claimed isolated

polynucleotide molecules having the sequences SEQ ID NO:2 and SEQ ID NO:4. Pro-

Mold & Tool Co. v. Great Lakes Plastics, Inc., 75 F.3d 1568, 1573, 37 USPQ2d 1626,

1629 (Fed. Cir. 1996). In our judgment, the only reason or suggestion to modify the

references to arrive at the present invention comes from appellants' specification.

Accordingly, we reverse the rejection of claims 22, 23, 25 and 26 under 35

U.S.C. ' 103.

The obviousness-type double patenting rejections are based on the same

reasoning as the rejection of claims 22, 23, 25 and 26 under 35 U.S.C. ' 103.

Accordingly, we reverse the rejection of claims 22, 23, 25 and 26 under obviousness-

type double patenting over claims 1-4 of Steeg I, or Steeg II, in view of Mullis.

REVERSED

SHERMAN D. WINTERS Administrative Patent Judge	)))))) BOARD OF PATENT
WILLIAM F. SMITH Administrative Patent Judge	)) APPEALS AND)) INTERFERENCES
DONALD E. ADAMS Administrative Patent Judge	)))

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